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Date: March 4, 2005 Name: Carolyn Beason-Wright Signature: Carolyn Beason-Wright

BRINKS HOFER GILSON & LIONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of:	Fred T. Parker, et al.
Appln. No.:	09/905,017
Filed:	July 13, 2001
For:	MEDICAL DEVICE INCLUDING TUBE HAVING A BRAID AND EXPANDED COIL
Attorney Docket No:	8627/114

Examiner: Roz Maiorino
Art Unit: 3763

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
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Alexandria, VA 22313-1450

TRANSMITTAL

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☒ Return Receipt Postcard

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						Small Entity			Not a Small Entity	
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Total		Minus				x $25=			x $50=	
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First Presentation of Multiple Dep. Claim						+$180=			+ $360=	
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Respectfully submitted,

March 4, 2005
Date

Lawrence A. Steward (Reg. No. 32,309)

Certificate Under 37 CFR 1.8(a)

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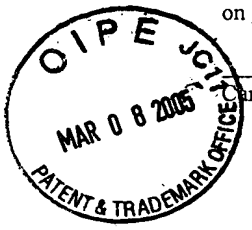
on March 4, 2005

Carolyn Beason-Wright

Carolyn Beason-Wright



PATENT

Case No. 8627/114

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	)	
	)	Art Unit: 3763
Fred T. Parker, et al.	)	
	)	Examiner: Roz Maiorino
Serial No.: 09/905,017	)	
	)	
Filed: July 13, 2001	)	
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For: MEDICAL DEVICE INCLUDING TUBE HAVING A BRAID AND EXPANDED COIL	)	

BRIEF OF APPELLANT

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This appeal is taken from the decision of the Examiner dated August 26, 2004, finally rejecting claims 1-12, 14 and 19 of the present application. Appellant timely filed his Notice of Appeal to the final rejection on January 12, 2005.

I. REAL PARTY IN INTEREST

The real party in interest in this matter is the Assignee of the application, Cook Incorporated.

II. RELATED APPEALS AND INTERFERENCES

There are no known prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-21 have been presented for examination.

Claims 1-12, 14 and 19 stand finally rejected and are appealed herein.

Claims 13, 15-18 and 20-21 have been canceled.

IV. STATUS OF AMENDMENTS

A Response to Final Action was filed by the Applicants on October 20, 2004, which response did not result in allowance of any of the claims. Applicants did not present any amendments in the Response to Final Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is drawn to a medical device, such as a device for expanding a narrowed or obstructed passage in a patient, or a device for introducing a liquid medicament or a medical interventional apparatus therethrough to a discrete location in the patient's anatomy. Examples of medical interventional apparatuses that may be introduced in this manner through the inventive device include a catheter and a stent.

Many medical devices that are used for the purposes listed above are provided with either a coil or a braid reinforcement in the wall of the device. A coil is known to provide superior kink resistance. Once a device has kinked,

medicaments or medical interventional devices cannot be passed through the lumen of the kinked device. As a result, the device must be removed, and another device must be introduced into the patient and once again advanced through the vascular system to the desired site. The presence of a coil is known to inhibit kinking. However, if the medical device is subjected to an axial force during use that tends to elongate it, a process known as "necking" may occur. Necking is the undesirable reduction in the inner and/or outer diameter of the device during use. The use of a coil as a reinforcement leaves the device susceptible to necking.

Unlike a coil, a braid provides relatively little kink resistance to a device. However, a braid is known to advantageously enhance the torqueability and pushability of the device, features that are only minimally provided by a coil. A braid is also useful to inhibit necking. (Page 2, line 26 to page 3, line 16)

In order to achieve the beneficial aspects of each type of reinforcement, some known medical devices utilize both a coil and a braid. Generally, these known devices utilize a metallic coil that is surrounded by a mesh-type braid. Normally, the device is structured such that the braid maintains the coil in a radially compressed condition. (Page 3, line 17 to page 4, line 4)

It is also known to utilize a coil in a device, wherein the coil is maintained in a radially expanded condition. One such device is disclosed in U.S. Patent No. 5,700,253, cited in the specification of the present application (Page 4, line 8) and by the Examiner in the final Office Action in the present case. However, U.S. Patent No. 5,700,253 does not teach or suggest the use of a second reinforcement, such as a braid, in combination with the radially expanded coil.

Maintaining a coil in a stressed radially expanded condition allows for a medical device with a wall which is thinner than might conventionally be required without this feature. It also provides the medical device with enhanced flexibility and springiness. During use, the medical device attempts to straighten in the body, making it easier to control advancement of the device in the patient. In addition, a stressed coil provides significant advantages during manufacture of the device, and in particular, better control over the wall thickness of the device. (Page 11, lines 14-22)

The present application includes two independent claims, namely claims 1 and 19. Claim 1 is directed to a medical device (10) comprising a tube (11), wherein the tube (11) comprises a coil (14) in a stressed, radially expanded condition. A braid (16) extends over at least part of the coil (14), and a polymeric layer (18) is positioned over and contacts at least the coil (14). The polymeric layer (18) maintains the coil (14) in the stressed, radially expanded condition. (Page 10, lines 4-16)

Claim 19 is directed to a medical device (10) comprising a tube (11), wherein the tube (11) comprises a metal coil (14) in a stressed, radially expanded condition. The metal coil (14) comprises flat wire. (Page 10, line 8) A metal braid (16) extends over at least part of the coil (14). (Page 10, line 11) A substantially imperforate polymeric bonding layer (18) is positioned over and contacts at least the coil (14). (Fig. 1) The polymeric layer (18) is heat shrinkable tubing comprising at least one of nylon, polyurethane and PTFE. (Page 10, lines 18-21; Original claim 8) An inner PTFE liner (20) is disposed beneath and in contact with at least part of the coil (14). (Page 11, line 8) The polymeric layer (18) maintains the coil (14) in the stressed, radially expanded condition by adhesion to the coil (14) by thermal bonding to it. (Page 10, lines 15-18) The tube (11) has an outer diameter no greater than about 1 mm. (Page 10, line 5)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-8, 12 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,700,253 to Parker ("Parker") in view of U.S. Patent No. 5,462,523 to Samson ("Samson I").[1]

2. Claims 9-11 and 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Samson I, and further in view of U.S. Patent No. 6,053,903 to Samson ("Samson II").

[1] The final Office Action indicates that claims 20 and 21 were also subject to this rejection. However claims 20 and 21 were cancelled in Applicants' amendment mailed May 3, 2004.

VII. ARGUMENT

ISSUE 1.

Claims 1-8, 12 and 14.

Claims 1-8, 12 and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Samson I. According to the Examiner, Parker discloses all of the features of claim 1 except the presence of a braid extending over a coil. Samson I was cited for teaching a braid extending over a coil. According to the Examiner, it would have been obvious to have combined Parker with Samson I because, according to Samson I, "the braid will provide extra support for the coil and allows for better maneuverability of the catheter tip."

The present application is directed to a medical device comprising a tube having a coil in a stressed, radially expanded condition, a braid extending over at least part of the coil, and a polymeric layer positioned over and contacting at least the coil. The polymeric layer maintains the coil in its stressed radially expanded condition. The medical device is particularly applicable for various uses that require small diameter structures, such as a device for use in the expansion of a narrowed or obstructed bodily passage, as a conduit for introducing a medicament or other medical device therethrough, or as a sheath for providing access deep into the vascular system of a patient.

Since the inventive device includes both a coil and a braid, it receives the particular advantages of each. It is known that the use of a coil in a medical sheath increases the flexibility of the device, and inhibits kinking. Flexibility of a sheath, particularly at the distal end, is an important feature of a sheath. This is particularly true when the sheath is to be used to access tortuous passageways. For a sheath to be able to bend in those passageways without kinking, the sheath material on the outer part of the bend must be able to stretch, and the corresponding sheath material on the inner part of the bend must compress. When a coil is incorporated into a sheath, the distance between the coil turns on the outside of the bend can elongate or increase very easily with minimum force, thereby allowing the sheath to stretch at the outer bend portion. At the same time, the distance between the turns on the inside of the coil decreases, allowing the sheath to compress at the inner bend portion. As a

result, a coiled sheath achieves the flexibility to navigate the tortuous bends, and then revert to its original shape.

A braid, on the other hand, comprises overlapping woven fibers or filaments. The woven nature of a braid causes it to resist substantial axial expansion and compression of the type that occurs with a coil. Therefore, a braid does not exhibit the degree of flexibility and kink resistance associated with a coil. Rather, a braided structure is known to provide favorable pushability, trackability and torqueability, when compared to a coiled structure. Thus, in those applications wherein it is necessary to apply torque to a sheath to force it through passageways, the woven nature of a braid makes it superior to a coil for that particular feature.

Thus, although braids and coils are each capable of providing beneficial attributes to a sheath, the two types of structures address different problems that may be encountered when attempting to pass a sheath through the vasculature.

The present invention combines the advantages of each, by providing a device that incorporates both a braid and a coil. Notwithstanding the combination, the beneficial aspects of each type of reinforcement can be controlled and/or adjusted as desired, such as by varying the length of the braid so that it can extend over all, or alternatively, a portion of the coil (see, e.g., claim 1). When a coil and a sheath are specifically arranged in a medical device, the beneficial aspects of each can be achieved. In addition, the inventive device can be constructed to have portions of different flexibility. This can be achieved, for example, by varying the durometer of the outer polymeric layer from one section to another (see, e.g., claim 14), or by extending the coil distally beyond the distal end of the braid. As a result, the device can be structured to maintain the flexibility and kink resistance at the tip that is provided by the coil, and to separate this flexible and kink resistant distal section from a relatively stiffer and more torqueable section that includes a coil/braid combination.

The structure of the claimed device provides additional advantages that go beyond the mere combination of a coil and a braid. As specified in each claim, the polymeric layer maintains the coil in a stressed, radially expanded condition. As stated previously, maintaining a coil in a stressed radially expanded condition allows a

medical device to have a wall which is thinner than might conventionally be required without this feature, and also provides the medical device with enhanced flexibility and springiness. In addition, a stressed coil provides significant manufacturing advantages.

In the final Office Action, the Examiner cited the primary Parker reference as teaching a device having a coil in a stressed radially expanded condition. The Examiner acknowledged that Parker does not teach a braid extending over the coil. Samson I was cited for teaching a braid extending over a coil. The Examiner stated that it would have been obvious to combine the teachings of Parker and Samson I because "according to Samson the braid will provide extra support for the coil and allows for better maneuverability of the catheter tip." Applicants respectfully disagree with the Examiner's characterization of the Samson I reference, as well as with the combination of references. When properly construed, Samson I does not teach the features recited by the Examiner, and in fact, is not a proper citation against the present claims in any event.

As specified by the Examiner, the cited Parker patent teaches a sheath that includes a coil that is compression fitted around the inner liner of the sheath. The sheath does not also include a braid, nor does the patent include any suggestion for incorporating a braid into the sheath. In fact, since the outer tube in Parker melts and connects to the inner tube through the turns of the coil, one skilled in the art might have concluded that a braid would be particularly inappropriate for the Parker structure, because the presence of a braid would inhibit the flow of the melted outer tube through the coil turns. Failure of flow between the coil turns would prevent the mechanical connection of the outer tube to the inner liner, and thereby defeat the express and intended purpose of the patent. The inventive device, on the other hand, need not include an inner liner; therefore there is no particular concern that the connection between the outer tube and an inner liner might be insufficient. Rather, the coil is stretched in a stressed, radially expanded condition and maintained in that condition during formation. Torsional control is not a subject of the cited Parker patent, and enhanced torqueability of the type achievable with the use of a braid in the inventive structure would not be achieved by the cited Parker structure.

The Samson I patent is directed to a different field of art than the present invention. This patent, titled DRUG DELIVERY SYSTEM, relates to the field of medical perfusion. The delivery catheter taught therein is used for delivering a medicament to a target site within the body by perfusion through a plurality of openings along the distal tip of a perfuser. The tip section that includes the openings includes two primary components, namely an inner stiffener portion which is relatively porous, and an outer perfuser layer which is less porous and controls the flow of the fluid through the perfusion openings. The inner stiffener may be a coil, and the outer perfuser layer may be a braided tube. Other embodiments, however, illustrate that a certain amount of interchangeability is possible between the coil and the braid. Another embodiment includes two braids, and omits a coil altogether. Yet another embodiment combines an elongated tube with a braid, and also omits a coil.

In Samson I, the coil and the braid are cooperatively arranged to provide a series of openings through which an agent, such as a liquid, can pass from the interior of the device to the exterior environment. See, e.g., Col. 3, line 61 to Col. 4, line 4. The fact that the coil and braid are interchangeable, and that the coil may even be omitted altogether, indicates that these structures are not provided to enhance flexibility, kink resistance and torqueability, but rather, for other reasons, in this case, to form perfusion openings in a tip structure. In fact, from the teaching of Samson I, there is no reason to believe that flexibility, kink resistance and torqueability would even be achieved by his perfuser tip. It appears that the recited structure is merely provided because the coil and braid are capable of being aligned in a manner to form perfusion openings of a controllable and predetermined size therebetween. This is abundantly clear when the reference is read as a whole, since the desired effect can be achieved by omitting either the coil or the braid altogether, and/or by replacing the coil or braid with an elongated tube. Flexibility, kink resistance and torqueability, if they are considerations of the perfuser tip at all, are at best collateral features of the Samson I device. A skilled artisan confronted with the challenge of providing an introducer sheath having these desirable properties would not be drawn to the teachings of Samson I.

It is well known that the patent examiner carries the burden of establishing a *prima facie* case of obviousness. *In re Warner, et al.*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967). A *prima facie* case of obviousness based upon a combination of prior art references requires some teaching, suggestion or motivation to combine the references. *In re Rouffet*, 149 F.3d 1350, 1355 (citing *In re Geiger*, 815 F.2d 686, 688, (Fed. Cir. 1998). The Federal Circuit has noted that this requirement serves "to prevent the use of hindsight based on the invention to defeat patentability of the invention..." *Id.* at 1357. The Federal Circuit has summarized the Examiner's duty as follows: "[T]he Examiner must show reasons that the skilled artisan, *confronted with the same problems as the inventor and with no knowledge of the claimed invention*, would select the elements from the cited prior art references for combination in the manner claimed." *Id.* (emphasis added).

In applying the Samson I reference, the Examiner stated that Samson I teaches that the braid will provide extra support for the coils and allow for better maneuverability of the tip. Applicants respectfully disagree with the Examiner's characterization of Samson I. As illustrated in Figs. 1 and 2, the Samson device comprises a proximal fitting 102, an elongated catheter body 108, and a perfusion tip 110. The maneuverability of the distal portion of the Samson device is provided by the flexibility built into the catheter body 108, and not by the coil/braid arrangement of the perfuser tip section 110. This flexibility is achieved by forming catheter body 108 of two or three discrete segments, each differing in flexibility. The most flexible portion is provided "near" the perfusion tip 110. (Col. 4, line 28). This arrangement is said to allow the catheter assembly to be maneuvered into very tight portions of the body's vasculature (Col. 4, lines 29-32).

Thus, the flexibility and maneuverability of the Samson device is provided by the distal portion of catheter body 108 (which is constructed according to a certain prior art patent to Engelson cited in Samson I), and not by the braid of the perfuser tip 110 as indicated by the Examiner in her statement supplying the justification for applying this reference in the Office Action. Although the perfuser tip may perhaps be constructed in a manner such that it is also flexible, that is not the purpose of this structure. The person of ordinary skill in the art would interpret the teachings of Samson I as providing a flexible

portion "near the perfusion tip 110", and not from the coil/braid arrangement of the perfusion tip. The coil/braid structure of the perfusion tip is not provided to supply maneuverability, contrary to the Examiner's statements in the Office Action.

The mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness. See, *In re Fritch,* 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). The Examiner must explain why the prior art would have suggested to one of ordinary skill in the art the desirability of the modification. *Fritch*, 972 F.2d at 1266, 23 USPQ2d at 1783-84. The Examiner's explanation in this case misconstrues the actual teaching of Samson I, as well as the manner in which the reference would be interpreted by one of ordinary skill in the art.

Applicants also respectfully disagree with the propriety of the combination of Parker and Samson I in the first place. In particular, the Examiner's stated rationale for the combination of Parker and Samson I is that "according to Samson the braid will provide extra support for the coil and allows for better maneuverability of the catheter tip." However, in order to properly combine two or more references in an obviousness determination, there must be some suggestion, motivation or teaching in the prior art whereby the person of ordinary skill in the art would have selected the components that the inventor selected and use them to make the new device. *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1351, 48 USPQ2d 1225 (Fed. Cir. 1998); See also, *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997). No such suggestion, motivation or teaching is present in the instant case.

Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing, in whatever form, must be "clear and particular." *Winner International Royalty Corp. v. Wang.*, 202 F.2d 1340, 53 USPQ2d 1580 (Fed. Cir. 2000). This was held to be so in *Winner International* even though the relevant field was very broad, the first reference taught all of the claim elements except one (in that case, a self-locking ratcheting), the second reference taught the element missing from the first, and the references were within the same field. No "clear and particular" showing has been made in the instant case.

As a corollary to the above proposition concerning the propriety of combining references, the *absence* of a suggestion to combine is considered to be dispositive in an obviousness determination. *Gambro Lundia AB, supra.* In the present case, it is only after hindsight is improperly employed that the invention can be reconstructed from the teachings of the cited art. No suggestion to combine is present.

Therefore, for at least the above reasons, Applicants respectfully submit that claims 1-8, 12 and 14 are allowable over the cited art of record.

ISSUE 2.

Claims 9-11 and 19.

Claims 9-11 and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Samson I, and further in view of Samson II. Claim 9 depends on claim 8, which depends on claim 1. Claim 9 adds the limitation that the polymeric layer (18) is encased within an additional layer of heat-shrinkable tubing. Claim 10 depends from claim 2, which depends on claim 1. Claim 10 adds the limitation that the polymeric layer (18) is thermally bonded to the coil. Claim 11 depends on claim 3, which depends on claim 1. Claim 11 adds the limitation that the inner liner (20) comprises PTFE.

Parker and Samson I were cited for the reasons specified above. Samson II was cited for teaching a medical device with a tube comprising a polymeric layer made from nylon or PTFE, and a heat shrinking tube with thermally bonded coils. Samson II, however, neither teaches nor suggests combining a coil and a braid in the manner of the present invention to achieve the benefits of flexibility, kink resistance and torqueability. Thus, Applicants respectfully submit that claims 9-11 are allowable for at least the same reasons that claims 1-8, 12 and 14 are allowable.

Claim 19 is an independent claim to a medical device that is more narrowly drawn than independent claim 1. For example, the polymeric outer bonding layer (18) is substantially imperforate, and the device includes an inner PTFE liner (20) disposed beneath and in contact with at least part of the coil (14). The tube (11) has an outer diameter no greater than about 1 mm.

The perfuser tip 110 of Samson I is not substantially imperforate. Rather, in view of the function of the tip to allow perfusion of liquids therethrough, the tip is provided with a multiplicity of perfusion openings. Even if there would have been motivation to combine Parker with Samson I in the rejection of independent claim 1, which Applicants dispute for the reasons specified previously, an even less compelling case can be presented for combining the references and citing them against claim 19, wherein the outer polymeric layer is substantially imperforate. Absent the use of hindsight, one or ordinary skill in the art would not combine the teachings of these references in the manner in which they have been applied in the present case.

Furthermore, the use of a perfusion tip of Samson I can fairly be said to teach away from the use of an imperforate tip in the device of claim 19. A reference which leads one away from the claimed invention cannot be used to render it unpatentably obvious. See, e.g., *Dow Chemical Co. v. American Cyanamid Co.*, 816 F.2d 617, 2 USPQ2d 1350 (Fed. Cir. 1987); *In re Grasseli et al.*, 713 F.2d 731, 218 USPQ 269 (Fed. Cir. 1983). Thus, Applicants respectfully submit that this reference is inappropriate for use in the present rejection. Samson II does not teach or suggest the use of a coil/braid combination. Without the use of hindsight, a medical device having the claimed structure with an imperforate tip cannot be fairly gleaned from the cited combination.

Thus, Applicants respectfully submit that claim 19 is allowable for at least the same reasons that claims 1-12 and 14 are allowable.

VIII. CONCLUSION

For the foregoing reasons, Applicants respectfully submit that the grounds for the Examiner's rejections of claims 1-12, 14 and 19 are not well taken, and should be reversed by this Board.

Respectfully submitted,

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CLAIMS APPENDIX

1. A medical device (10) comprising a tube (11), wherein the tube (11) comprises:

a coil (14) in a stressed, radially expanded condition;

a braid (16) extending over at least part of the coil (14); and

a polymeric layer (18) positioned over and contacting at least the coil (14);

the polymeric layer (18) maintaining the coil (14) in the stressed, radially expanded condition.

2. The medical device (10) according to claim 1, wherein the polymeric layer (18) maintains the coil (14) in the stressed, radially expanded condition by adhesion to the coil (14).

3. The medical device (10) according to claim 1, further comprising an inner liner (20) beneath and in contact with at least part of the coil (14).

4. The medical device (10) according to claim 1, wherein at least one of the coil (14) and the braid (16) comprises a metal.

5. The medical device (10) according to claim 1, wherein the braid (16) comprises a plurality of crossed wires (22).

6. The medical device (10) according to claim 5, wherein the wires (22) are circular in cross-section.

7. The medical device (10) according to claim 1, wherein the coil (14) comprises flat wire.

8. The medical device (10) according to claim 1, wherein the polymeric layer (18) comprises at least one of nylon, polyurethane and PTFE.

9. The medical device (10) according to claim 8, wherein the polymeric layer (18) is encased within an additional layer of heat-shrinkable tubing.

10. The medical device (10) according to claim 2, wherein the polymeric layer (18) is thermally bonded to the coil (14).

11. The medical device (10) according to claim 3, wherein the inner liner (20) comprise PTFE.

12. The medical device (10) according to claim 1, wherein the tube (11) has an outer diameter no greater than about 2 mm.

13. Cancelled.

14. The medical device (10) according to claim 1, wherein the polymeric layer (18) comprises at least two discrete longitudinal segments (28 and 30) of differing durometer.

15-18. Cancelled.

19. A medical device (10) comprising a tube (11), wherein the tube (11) comprises:

a metal coil (14) in a stressed, radially expanded condition, the metal coil (14) comprising flat wire:

a metal braid (16) extending over at least part of the coil (14);

a substantially imperforate polymeric bonding layer (18) positioned over and contacting at least the coil (14), wherein the polymeric layer (18) is heat shrinkable tubing comprising at least one of nylon, polyurethane and PTFE; and

an inner liner (20) beneath and in contact with at least part of the coil (14), the liner (20) comprising PTFE;

wherein the polymeric layer (18) maintains the coil (14) in the stressed, radially expanded condition by adhesion to the coil (14) by thermal bonding to it; and

wherein the tube (11) has an outer diameter no greater than about 1 mm.

20-21. (Cancelled)